

REMARKS

The Final Office Action mailed August 8, 2007 has been received and reviewed. Prior to the present communication, claims 1, 2, 4-13, 15-24, 26-36 were pending in the subject application. Claims 1, 4, 6, 7, 9, 10, 12, 17, 18, 21, 23, 28, 29, 32, and 34-36 have been amended as herein above set forth, claims 2, 5, 8, 13, and 24 have been cancelled, and claims 37 and 38 have been added. Accordingly, claims 1, 4, 6, 7, 9-12, 15-23, and 26-38 are pending after the amendments. It is respectfully submitted that no new matter has been added by way of the present amendments. Reconsideration of the subject application is respectfully requested in view of the above amendments and the following remarks.

Rejections based on 35 U.S.C. § 112

Claims 1, 2, 4-13, 15-24, and 26-36 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to point out and distinctly claim subject matter which the Applicant regards as the invention. In particular, the Office states that the limitation “if” renders the scope of the independent claims 1, 12, and 23 indefinite.¹ In response, claims 1, 12, and 23 have been amended to remove the clauses beginning with the term “if,” thereby overcoming the § 112 rejection. It is respectfully submitted that, as amended, claims 1, 12, and 23 are definite under 35 U.S.C. § 112, second paragraph. Each of claims 4, 6, 7, 9-11, 15-22, and 26-38 depends, either directly or indirectly, from one of independent claims 1, 12, and 23, and, as such, are believed to be similarly definite.² Accordingly, withdrawal of the 35 U.S.C. § 112, second paragraph, rejection of claims 1, 4, 6, 7, 9-12, 15-23, and 26-38 is respectfully

¹ See *Office Action* at pg. 3, ll. 4-15.

² See 37 C.F.R. § 1.75(c) (2006).

requested. Claims 2, 5, 8, 13, and 24 been cancelled by way of the present amendment and, accordingly, the rejections of these claims have been rendered moot.

Support for Claim Amendments

It is proposed that each of independent claims 1, 8, and 15 be amended as set forth herein. Support for these claim amendments may be found in the Specification, for example, at paragraph [0018].

Rejections based on 35 U.S.C. § 103

A.) Applicable Authority

Title 35 U.S.C. § 103(a) declares, a patent shall not issue when “the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” The Supreme Court in Graham v. John Deere counseled that an obviousness determination is made by identifying: the scope and content of the prior art; the level of ordinary skill in the prior art; the differences between the claimed invention and prior art references; and secondary considerations.³ To support a finding of obviousness, the initial burden is on the Office to apply the framework outlined in Graham and to provide some reason, suggestion, or motivation, found either in the prior art references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the prior art reference or to combine prior art reference teachings to produce the claimed invention.⁴ Recently, the Supreme Court elaborated, at pages 13-14 of the *KSR* opinion, that “it will be necessary for [the Office] to look at interrelated teachings of multiple [prior art

references]; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by [one of] ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the [patent application].”⁵

B.) Obviousness Rejection Based upon U.S. Patent No. 5,253,164 to Holloway in view of U.S. Patent No. 4,491,725 to Pritchard

Claims 1, 2, 4-7, 9-13, 15-28, 20-24, 26-29, and 31-36 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,253,164 to Holloway (hereinafter the “Holloway reference”) in view of U.S. Patent No. 4,491,725 to Pritchard (hereinafter the “Pritchard reference”). As the Holloway reference and the Pritchard reference, whether taken alone or in combination, fail to teach or suggest all of the limitations of the rejected claims, Applicant respectfully traverses this rejection, as hereinafter set forth. Further, claims 2, 5, 13, and 24 have been cancelled by way of the present communication and, accordingly, the rejections of these claims have been rendered moot.

Independent claim 1, as amended hereinabove, recites, in part, a system for conditioning clinically related billing items. In particular, the system includes a conditioning engine for determining whether the preliminary billing item complies with the at least one regulatory guideline. In this way, the system ensures that the preliminary billing item is payable under present government-imposed regulations. Neither the Holloway reference nor the Pritchard reference describe determining whether a billing item complies with regulatory

³ *Graham v. John Deere Co.*, 383 U.S. 1 (1966).

⁴ *See, Application of Bergel*, 292 F. 2d 955, 956-957 (1961).

⁵ *KSR v. Teleflex*, No. 04-1350, 127 S.Ct. 1727 (2007).

guidelines. Instead, the Holloway reference describes utilizing internal administrative guidelines to validate medical claims.⁶ The Pritchard reference converts a patient's medical-procedure information into billable information that is received at an insurance provider without comparing the medical-procedure information against a guideline.⁷ Further, the Office has indicated that neither Holloway nor Pritchard teach a regulatory guideline.⁸

However, the Office states that Holloway teaches physical incentives resulting from changes related to Medicare payment schedules, thus, implying that the feature of determining whether the billing item complies with regulatory guidelines is obvious in light of the present marketplace conditions. Rather than pointing to specific information in the cited references or other prior references that particularly suggest the comparing claims against regulatory guidelines, the Office has supplemented a limitation *sua sponte*. Nowhere does the Office particularly identify any suggestion or teaching, such as the identification of the relevant art, the level of ordinary skill in the art, the nature of the problem to be solved, or any other factual findings that might serve to support a proper obviousness analysis.⁹ Because no specific art or documentary evidence is referenced to support this assertion; as such, the Office has taken "Official Notice" and based the § 103(a) rejection on general skill in the art.

A prior art rejection should be based on an actual prior art reference while relying on Official Notice only where the facts asserted are well-known or of common knowledge in the

⁶ See *Holloway reference* at col. 3, ll. 38-68.

⁷ See *Pritchard Reference* at col. 3, ll. 29-53.

⁸ See *Office Action* at pg. 8, ll. 15-18.

⁹ See, e.g., *Pro-Mold & Tool*, 75 F.3d 1568, 1573 (Fed. Cir. 1996).

art.¹⁰ *A fortiori*, assertions of technical facts in areas of esoteric technology (e.g., automated determination whether a billing item complies with stored regulatory guidelines) must always be supported by citation to some reference work recognized as standard in the pertinent art.¹¹

In addition, “it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known in the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue.”¹² The Office states that the Holloway reference describes physician incentives resulting from “upcoding” a fee-payment schedule to correspond with higher fee schedules.¹³ Based on this assumption, the Office falsely concludes that verifying claims against a Medicare/Medicaid fee payment schedule is obvious in the marketplace.¹⁴ The existence of fraudulent “upcoding” activity, and its input on the Medicare/Medicaid fee-payment schedule,¹⁵ is unrelated to the issue of clinically conditioning related billing items, as presently claimed, to determine sufficiency. As such, the claims are nonobvious since the adaptation set forth by the Office is unsupported.

“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to

¹⁰ MPEP § 2144.02(A); *In re Ahlert*, 424 F.2d 1088, 1091 (CCPA 1970) (finding that notice of facts beyond the record which may be taken by the Examiner must be “capable of such instant and unquestionable demonstration as to defy dispute”).

¹¹ *Id.*

¹² *KSR v. Teleflex*, 2007 WL 1237837 at *14.

¹³ See *Office Action* at pg. 8, ll. 15-18.

¹⁴ *Id.* at pg. 9, ll. 3-9.

¹⁵ See *Holloway reference* at col. 1, ll. 39-68.

support the legal conclusion of obviousness.”¹⁶ In this instance, the Office has not set forth the proper foundation for an Official Notice, nor established that the process step of determining whether a billing item complies with regulatory guidelines is well-known to a person of ordinary skill in the art. As such, the asserted general conclusion concerning what is common knowledge to one of ordinary skill in the art without some concrete evidence in the record to support this finding will not support an obviousness rejection.¹⁷ The Office’s assertion of Official Notice is considered traversed; accordingly, the Office must provide documentary evidence if the rejection is to be maintained.¹⁸

Moreover, without demonstrating as obvious the process step of determining whether a billing item complies with regulatory guidelines, the proposed combination offered by the Office does not meet the limitations of the claimed subject matter, and as a matter of law the Office’s rejection cannot stand.

Independent claim 12, as amended hereinabove, recites, in part, a method for conditioning clinically related billing items, where the method includes “analyzing, as a condition precedent to transmitting the preliminary billing item to a paying party, the preliminary billing item by *comparison against at least one regulatory guideline* to determine compliance therewith” (emphasis added). Independent claim 23, as amended hereinabove, recites, in part, one or more computer-readable storage media having computer-executable instructions embodied thereon that, when executed, perform a method. In particular, the method includes “analyzing, as a condition precedent to transmitting the preliminary billing item to a paying

¹⁶ *KSR v. Teleflex*, 2007 WL 1237837 at *14 (citing *In re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006)).

¹⁷ MPEP § 2144.03(B); *In re Lee*, 277 F.3d 1338, 1344 (Fed. Cir. 2002).

¹⁸ 37 C.F.R. § 1.104(d)(2).

party, the preliminary billing item by *comparison against at least one regulatory guideline* to determine compliance therewith” (emphasis added). As discussed above, the Holloway reference and the Pritchard reference, whether taken alone or in combination, fail to teach or suggest the feature analyzing the preliminary billing item by comparison against at least one regulatory guideline to determine compliance therewith. Accordingly claims 12 and 23, as amended are in condition for allowance.

As such, for at least the reasons stated above, Applicant suggests that claims 1, 12, and 23 are not anticipated by Holloway in view of Pritchard and are in condition for allowance. Each of claims 4, 6, 7, 9-11, 15-22, and 26-38 is believed to be in condition for allowance based at least upon their dependency from claims 1, 12, and 23, respectively, and such favorable action is respectfully requested.¹⁹

B.) Obviousness Rejection Based upon the Holloway reference in view of the Pritchard reference and U.S. Patent No. 5,235,702 to Miller

Claims 8, 19, and 30 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the Holloway reference in view of the Pritchard reference and U.S. Patent No. 5,235,702 to Miller (hereinafter the “Miller reference”). As the Holloway reference, the Pritchard reference, and the Miller reference, whether taken alone or in combination, fail to teach or suggest all of the limitations of the rejected claims, Applicant respectfully traverses this rejection, as hereinafter set forth. Further, claim 8 has been cancelled by way of the present communication and, accordingly, the rejection of this claim have been rendered moot.

¹⁹ See 37 C.F.R. § 1.75(c) (2006).

Claim 19 depends indirectly from claim 12, as amended hereinabove, and claim 30 depends indirectly from claim 23, as amended hereinabove. As previously mentioned, the Holloway reference and the Pritchard reference fail to describe the following limitation of claims 19 and 23, “analyzing, as a condition precedent to transmitting the preliminary billing item to a paying party, the preliminary billing item by comparison against at least one regulatory guideline to determine compliance therewith.” The Office does not assert that the Miller reference teaches these claimed elements, rather, the Examiner merely asserts that the Miller reference discloses the “automated search for additional clinical documentation” feature of dependent claims 19 and 30. As such, Miller fails to cure the deficiencies of Holloway and Pritchard. As a result, it is respectfully submitted that dependent claims 19 and 30 are allowable based, in part, on their dependency from claims 12 and 23, respectively.²⁰ Accordingly, the proposed combination does not meet the limitations of the claimed subject matter and, as a matter of law, the Office’s rejection cannot stand.

NEW CLAIMS

Each of claims 37 and 38 has been added by way of the present communication. It is respectfully submitted that each of the added claims is supported by the as-file specification and drawings, and that no new matter has been added by way of the claim additions. Each of the claims 37 and 38 is believed to be in condition for allowance and such favorable action is respectfully requested.

²⁰ See 37 C.F.R. § 1.75(c) (2006).

CONCLUSION

For at least the reasons stated above, each of claims 1, 4, 6, 7, 9-12, 15-23, and 26-38 is believed to be in condition for allowance and such favorable action is respectfully requested. If any issues remain that would prevent issuance of this application, the Examiner is urged to contact the undersigned by telephone prior to issuing a subsequent action.

It is believed that no fee is due in conjunction with the present communication. However, if this belief is in error, the Commissioner is hereby authorized to charge any amount required to Deposit Account No. 19-2112, referencing attorney docket number CRNI.110509.

Respectfully submitted,

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